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## EU-25

## Biotechnology

## Update on the EU's Biotech Approval Process

## 2004

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**Report Highlights:**

In view of the failure of the EU's Council of Agricultural Ministers to authorize the import of Syngenta's Bt11 sweet corn for food purposes on April 26, Commissioner David Byrne of the Directorate General of Health and Consumer Protection has said that the Commission will approve Bt11 in late May or June. Monsanto's Roundup Ready Corn (NK603) is next in line for approval for import for feed and food purposes. If Bt11 is authorized for marketing, this would be the first approval since 1998 when the EU's unofficial moratorium went into effect. Currently, there are over 30 biotech products waiting approval by the EU.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Brussels USEU [BE2]  
[E3]

### Syngenta's Bt11 Sweet Corn

The EU is currently reviewing Syngenta's request to import Bt11 for food purposes. Of the 34 biotech products currently awaiting approval for marketing in the EU, Bt11 is the furthest along in the approval process.

Commissioner David Byrne of the Directorate General of Health and Consumer Protection has strongly stated that the Commission will approve Bt11 in late May or June 2004 in view of the Council of Agricultural Ministers failure to reach a decision on April 26. This will bring an end to the long and circuitous process that began in April 2000 when Syngenta submitted Bt11 for an initial risk assessment. An EU Scientific Committee on Food (SCF) issued a favorable risk assessment for this product on March 13, 2002.

Despite this positive assessment, a number of EU member states have continued to block the approval of this product. In December 2003, the Commission consulted with the 15 member states in the Standing Committee on the Food Chain and Animal Health. When no decision could be reached in this committee concerning the fate of Bt11, the matter was then referred to the EU's Council of Agricultural Ministers. Only the most controversial issues are referred to the ministerial level of the EU.

### Monsanto's Round Up Ready Corn (NK603)

Like Bt11, Monsanto's NK603 is wending its way through the same approval process. Monsanto has requested approval to import this product for processing for both feed and food purposes. In December 2000, Monsanto first submitted an application for the review and approval of this product. The European Food Safety Authority, taking over from the SCF, issued a positive risk assessment for NK603 in December 2003.

In February 2004, the Commission consulted with the 15 member states in the 2001/18 environmental regulatory committee on the release of genetically modified organisms. The member states failed to reach a decision to approve or disapprove the import of NK603 for feed purposes. On April 30, the member states met in the Standing Committee on the Food Chain and Animal Health to debate the authorization of NK603 for import for food purposes. This committee also failed to reach a decision.

Following a similar path as Bt11, NK603 will now be referred to the EU Council of Ministers, most likely the Agricultural or Environmental Council. Again, if the Council fails to reach a decision, the matter will then be referred to the Commission for a final decision.

### Recent European Food Safety Authority (EFSA) Risk Assessments

**In recent months, EFSA has issued positive risk assessments for the following biotech products:**

Product	Variety	Uses	Date Issued
Corn	NK603	Processing, Food, Feed	12/4/2003
Rapeseed	GT703	Processing, Feed	3/1/2004
Corn	MON863	Processing, Food, Feed	4/19/2004

It should be noted that EFSA owes its existence in part to the food safety problems, including BSE and dioxin that erupted in Europe in recent years. The main responsibility of EFSA is to provide scientific advice for Community legislation and policies in all fields having a direct or indirect impact on food and feed safety through the development of risk assessments, and to communicate these findings to the general public.

The January 28, 2002 adoption of the legal basis that created EFSA was hailed as a major milestone in the EU's efforts to increase consumer confidence in the safety of food and feed products.

### **Member State Objections**

On April 18, 2004 the EU implemented its new regulations on the labeling and traceability of biotech products. Previously, many member states argued that such regulations were needed to protect consumer and environmental interests. Commissioner Byrne has adamantly insisted that these concerns have now been met and that it is time for the member states to move on, and begin to approve the products.

In some instances, some member states such as Germany invoke the precautionary principle to justify their doubts about the safety of biotech products. Other member states such as France have raised specific objections about the interpretation of the results of the risk assessments and have called for additional studies.

An equally important concern for the member states has been the issue of the co-existence of conventional, organic and biotech agricultural practices. In July 2003, the Commission adopted a recommendation (2003/556/E) on co-existence setting out guidelines for the development of national strategies and best practices to ensure co-existence. The Commission stated "...that approaches to co-existence need to be developed in a transparent way, based on scientific evidence and in cooperation with all stake-holders concerned."

Austria and Italy have been particularly vocal critics of the Commission, insisting that mandatory EU-wide regulations are necessary to deal with this issue. Austria went so far as to attempt to institute a non-GMO production zone in the region of Upper Austria. The Commission ruled that Austria failed to present sufficient scientific evidence to warrant such a ban and denied the request.

### **Member State Positions on Bt11**

**In the latest vote that occurred on April 26 in the Agricultural Council on Bt11, the vote was as follows:**

For: United Kingdom, Netherlands, Sweden, Ireland, Italy and Finland. Previously Italy had voted against authorization in the regulatory committee phase of the debate.

Against: Denmark, Greece, Luxembourg, Austria, Portugal and France voted against.

Abstain: Germany, Belgium and Spain abstained. Previously, Spain had voted in favor in the regulatory committee phase of the debate.

**Member State Positions on NK603**

**In the vote that occurred on April 30 in the Standing Committee on the Food Chain and Animal Health on NK603 for food purposes, the vote was as follows:**

For: Sweden, Finland, Belgium, United Kingdom, France, Ireland, Italy, and Netherlands.

Against: Portugal, Greece, Denmark, Luxembourg, and Austria

Abstain: Germany, Spain

Since the February meeting when NK603 was up for approval for feed use, a number of member states have changed their positions:

- Italy voted against it for feed in February but in favor for food in April.
- Spain voted in favor for feed in February and abstained in April for food.
- And Portugal shifted from supporting it for feed in February to opposing it for food in April.

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**Related reports from USEU Brussels:**

Report Number	Title	Date Released
E24069	Antibiotic Resistance Marker Genes	4/21/04
E24045	Safe as Conventional Rapeseed	4/4/04
E23234	Bt11 Sweet Corn	12/9/03
E23233	Safe as Conventional Corn	12/8/03
E23231	European Food Safety Authority	12/8/03
E23170	Austria's Request for Ban on Use of GMOs Denied	9/8/03
These reports can be accessed through our website <a href="http://www.useu.be/agri">www.useu.be/agri</a> or through the FAS website <a href="http://www.fas.usda.gov/scripts/attacherep/default.asp">http://www.fas.usda.gov/scripts/attacherep/default.asp</a> .		